

U.S.S.N. 09/662,927

Filed: September 15, 2000

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

Claim 1 has been amended to define the device as not for drug delivery. Support for this amendment is found at page 5, line 16-21. New claims 34-36 specifically defines devices as described in this same portion of the specification.

Claim 1 has also been amended to incorporate the limitations of dependent claims 6 and 7, now cancelled. Claim 19 has been amended to incorporate the limitations of claim 23, now cancelled.

Claim 33 has been amended to refer to (1) multiple sensors rather than one or more; (2) require a response in the **sensors** (support is found at page 4, lines 3-6; and (3) incorporate the limitations of claim 31 or the language at page 3, lines 27-30.

Entry of this amendment to incorporate the limitations of the dependent claims into the independent claims and thereby narrow issues on appeal, in the event the application is not allowed, is earnestly solicited. Entry of the amendment does not increase the number of pending claims.

Rejections Under 35 USC 102 and 35 USC 103(a)

Claims 1-9, 19, 22, and 23 were rejected under 35 U.S.C. § 102(b) as disclosed by U.S. Patent No. 4,146,029 to Ellinwood. Claims of 1-9, 19, 22, 23, and 30-33 were rejected under 35 U.S.C. § 102(b) as disclosed by U.S. Patent No. 6,248,080 to Miesel, et al. Claims 27 and 28 were rejected under 35 U.S.C. § 103 (a) as obvious over Ellinwood in combination with U.S. Patent No. 5,411,551 to Winston, et al.

The Claimed Invention

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Claim 1 and claims dependent thereon, have been amended to exclude drug delivery devices. These claims are now limited to other types of medical implants, such as stents or diagnostic implants. The prior art does not disclose medical implants other than drug delivery devices. Claim 33 is drawn to the embodiment where the device includes multiple sensors. The prior art does not disclose devices including multiple sensors, instead disclosing devices that can have *different* types of sensors, but only one at a time that the device is responsive to (if any).

Ellinwood

As noted both above and by the examiner, Ellinwood discloses a drug delivery device which is responsive to external operator control (col. 3, lines 9-16). The examiner does not provide a specific citation in support of the statement that Ellinwood discloses sensing means. Col. 7, lines 1-52, refers to sensors, but does not state that they are part of the device. To the extent this sensor could be construed to be part of a "system", it is distinguished in claims 1 and dependent claims by virtue of the device not being for drug delivery. For claim 33, it is distinguished since it is clear that there is only one sensor to which the device is responsive. The only reference to sensors in the plural is with reference to plural devices. Accordingly, there is also no teaching motivating one to utilize multiple sensors for a single device. Indeed, one is led away by the teaching that one uses a single device-single sensor, in this case, to monitor effects of drug release.

Miesel, et al.

Miesel discloses an implantable medical device for measuring intracranial pressure or temperature, which is detected externally, in some cases using telemetric means.

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The device is not responsive to signals generated as a result of communication between the sensors and external, but is merely a data gathering device for external monitoring. To the extent the device includes any responsive element, it is for drug delivery (col. 6, lines 27-42).

Winston, et al.

Winston discloses only a stent that includes a sensor for glucose.

The Combination of Ellinwood and Winston

Ellinwood, as note above, only discloses devices for drug delivery. Winston discloses a stent with a glucose sensor. There is no teaching of how one could make a device responsive to data derived from the stent other than by incorporation of a drug. Accordingly, Ellinwood in combination with Winston cannot make obvious the subject matter of the claims.

Allowance of pending claims 1-5, 8, 9, 19, 22, 27, 28 and 30-36, is respectfully solicited.

Respectfully submitted,



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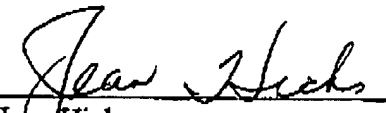
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**Certificate of Facsimile Transmission Under 37 C.F.R. § 1.8(a)**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being facsimile transmitted to the Assistant Commissioner for Patents, Washington, D.C. 20231 on the date shown below.

  
Jean Hicks

Date: December 20, 2002

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MARKED-UP VERSION OF AMENDED CLAIMS

**Marked Up Version of Amended Claims****Pursuant to 37 C.F.R. § 1.121**

1. (twice Amended). A system for monitoring and responding to the environment of an implanted device, wherein the device is not for drug delivery, comprising:

one or more sensors configured for monitoring data relating to variables selected from the group consisting of electrical, magnetic, mechanical, fluid flow, chemical, and thermal properties in the device or its environment in a patient, [and]

at least one actuator configured for implementing a response to the monitored data in the device by causing a configurational change in the device,

means for communication to one of a series of nested loops of information exchange, and  
an external input connected through loops to effectuate change in the device from the at  
least one actuator.

2. The system of claim 1 which includes a data storage means.

3. (Once Amended). The system of claim 2 wherein the data storage means is configured to be placeable on the device or contiguous to the device or within or on the body of the patient.

4. The system of claim 1 which includes a telemetry means.

5. The system of claim 4 wherein the telemetry means is an analog or digital electronic device.

Please cancel claims 6 and 7.

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8. (Once Amended). The system of claim 1 additionally comprising monitoring means configured for positioning external to the patient.

9. (Once Amended). The system of claim 1 wherein the sensor is configured to detect changes in pH, temperature, ion concentration, or analyte concentration.

19. (twice Amended). The system of claim 1 comprising transmitting and receiving means to the one or more sensors, wherein the transmitting and receiving means are suitable for transmitting or receiving data from a computer or phone communication means.

22. (Once Amended). The system of claim 1 further comprising means for remotely accessing the data.

Please cancel claim 23.

27. (Once Amended). The system of claim 1 wherein at least one sensor is configured to measure fouling of the device or at least one sensor over time.

28. (twice Amended). The system of claim [1] 36 wherein at least one sensor is configured to measure protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, and neointimal thickening of an arterial stent, resulting in an increase in thickness, mass and wall shear.

30. (Once Amended). The system of claim 1 comprising:

(a) one or more sensors for monitoring the general environment of the implanted device;

(b) monitoring means; and

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**MARKED-UP VERSION OF AMENDED CLAIMS**

(c) the one or more sensors configured for communicating information to the monitoring means and to each other, and configured for communicating commands to the actuator.

31. (Once Amended). The system of claim 30 wherein the one or more sensors communicate information to a computer transmitting the information to another computer via the internet.

32. The system of claim 31 wherein the transmission over the Internet to another computer is via a posting to the world wide web.

33. (Twice Amended). An implantable device comprising:  
[one or more] multiple sensors configured for monitoring at least one condition;  
at least one actuator configured for implementing a response to the monitored condition in the [device by causing a configurational change in the device] sensors other than drug delivery;

wherein the one or more sensors communicate information to a computer transmitting the information to another computer via the internet or through multiple levels of isolated or nested levels of information transfer, and

the one or more sensors and the at least one actuator configured for control by at least one apparatus external to the implantable device.

Please add new claims 34-36.

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**MARKED-UP VERSION OF AMENDED CLAIMS**

34. The system of claim 1 wherein the device is selected from the group consisting of therapeutic and diagnostic devices.

35. The system of claim 34 wherein the device is a diagnostic implant selected from the group consisting of spheres, pellets, wafers, slivers, chips, weaves, fabrics, and arrays.

36. The system of claim 34 wherein the device is a therapeutic support device selected from the group consisting of stents, stent-grafts, grafts, rings, hooks, sutures, wires, tissue conduits.